REMARKS

Upon entry of the above amendment, claims 1-9 will be pending in the present application. Applicants respectfully submit that the amendment of claim 1 does not add any new matter within the meaning of 35 USC §132. Accordingly, entry of the amendment is respectfully requested.

1. Rejection of claims 1-6 and 8 under 35 U.S.C. § 103(a)

The Official Action states that claims 1-6 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilking (U.S. Patent No. 5,698,217).

RESPONSE

Applicants respectfully traverse this rejection of claims 1-6 and 8. The cited reference does not establish a *prima facie* case of obviousness against the presently pending claims. To establish a prima facie case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in KSR International Co. v. Teleflex Inc. et al., Slip Opinion No. 04-1350, 550 U.S. __ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the

claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, supra, slip opinion at 13-15). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Amgen Inc. v. Chugai Pharm. Co., 18 USPQ 1016, 1023 (C.C.P.A 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A. The Presently Claimed Invention

The presently claimed invention as exemplified by currently amended independent claim 1 is directed to:

> A patch-containing packaging pouch comprising: a packaging pouch; and a patch, housed within the packaging pouch, in which a pressure-sensitive adhesive layer is formed on one side of a support, wherein the pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and bisoprolol or a pharmaceutically acceptable salt thereof, wherein the content of bisoprolol is 1 to 50% by mass in the pressure-sensitive adhesive composition, and relative humidity inside the packaging pouch at 25°C is maintained at 25% or less.

B. The Teachings of the Wilking Reference

The Wilking reference describes a transdermal drug delivery device containing a substantially water free carrier, a dissolved drug, a dessicant package, and a product package substantially impermeable to water vapor.

C. No *prima facie* Case of Obviousness has been shown by the Examiner

The Wilking reference does not disclose all of the limitations of the presently pending claims, as required by In re Wilson. In particular, the Examiner asserts that the Wilking reference describes "a patch containing packaging pouch comprising: a packaging pouch; and a patch, housed within the packaging pouch, in which a pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and a dissolved drug." See page 3 of the Official Action. However, the Wilking reference does not disclose the drug, bisoprolol or a pharmaceutically acceptable salt thereof, which is required by the presently pending claims.

Further, the Wilking reference does not disclose that the content of bisoprolol in the pressure-sensitive adhesive composition is 1-50% by mass as recited in presently pending claim 1. Nowhere in the Wilking reference is there any mention of the preferred content of any drug to be used in the aforementioned transdermal formulations. The preferred content of 1-50% by mass in the present pressure-sensitive adhesive composition is specific to bisoprolol, is not well known to persons of ordinary skill in the art, and is not at all recognized by the Wilking reference.

Further, the Wilking reference does not disclose that the patch-containing packaging pouch will have a relative humidity of 25% or less at 25°C as required by the presently pending claims. Because bisoprolol is unstable to humidity, it is necessary to set relative humidity to less than 25%. Nowhere in the Wilking reference is there any

mention of the relationship between relative humidity and the type of drug to be used in the transdermal formulation. Further, there is no suggestion in the Wilking reference that would motivate a person of ordinary skill in the art to prepare a patch-containing packaging pouch with bisoprolol as the drug, and possessing a relative humidity of 25% or less inside the packaging pouch as required by the presently pending claims. Accordingly, as the Wilking reference does not teach a specific relative humidity that is to be maintained inside the packaging pouch for bisoprolol or any other drug, the Wilking reference cannot render the presently pending claims obvious.

As such, the Wilking reference cited by the Examiner does not teach all of the limitations of the presently pending claims, as required by In re Wilson. Further, there is no suggestion in the Wilking reference that would motivate a person of ordinary skill in the art to read these missing elements into the Wilking reference. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness. Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-6 and 8.

2. Rejection of claim 7 under 35 U.S.C. § 103(a)

The Official Action states that claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilking, in view of Kanios et al. (U.S. Patent No. 6,905,016).

RESPONSE

Applicants respectfully traverse this rejection of claim 7. The cited references do not establish a *prima facie* case of obviousness against presently pending claim 7. The

requirements for establishing a *prima facie* case of obviousness, as previously discussed in Section 1, are incorporated herein by reference in their entirety.

A. The Presently Claimed Invention

As previously discussed in Section 1, the presently claimed invention as exemplified by currently amended independent claim 1 is directed to:

> A patch-containing packaging pouch comprising: a packaging pouch; and a patch, housed within the packaging pouch, in which a pressure-sensitive adhesive layer is formed on one side of a support, wherein the pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and bisoprolol or a pharmaceutically acceptable salt thereof, wherein the content of bisoprolol is 1 to 50% by mass in the pressure-sensitive adhesive composition, and relative humidity inside the packaging pouch at 25°C is maintained at 25% or less.

Dependent claim 7 incorporates the features recited in independent claim 1, and further recites "the pressure-sensitive adhesive contains at least one type of compound selected from the group comprising a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer."

B. The Teachings of the Wilking Reference

As previously discussed in Section 1, the Wilking reference describes a transdermal drug delivery device containing a substantially water free carrier, a dissolved drug, a dessicant package, and a product package substantially impermeable to water vapor.

C. The Teachings of the Kanois et al. Reference

The Kanois et al. reference describes a packaging system for a transdermal drug

delivery system that inhibits drug degradation during storage of the system prior to its use.

D. No *prima facie* Case of Obviousness has Been Shown by the Examiner

Neither the Wilking nor Kanois et al. references, taken alone or in combination, disclose all of the limitations of the presently pending claims, as required by In re Wilson. In particular, the Examiner asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the pressure-sensitive adhesive of Wilking to include an acrylic polymer pressure-sensitive adhesive as taught by Kanios et al. in order to use an adhesive that will not have a reaction with certain drugs." See page 5 and 6 of the Official Action. However, neither the Wilking nor the Kanois et al. references disclose the drug, bisoprolol or a pharmaceutically acceptable salt thereof, as required by presently pending claim 7.

Further, neither of the cited prior art references discloses that the specific content of bisoprolol in the pressure-sensitive adhesive composition is 1-50% by mass as required by presently pending claim 7. Nowhere in either of the prior art references cited by the Examiner is there any mention of the preferred content of any drug to be used in the aforementioned transdermal formulations. The preferred content of 1-50% by mass in the present pressure-sensitive adhesive composition is specific to bisoprolol, is not well known to persons of ordinary skill in the art, and is not at all recognized by either the Wilking or Kanois et al. references.

As previously discussed in Section 1, the Wilking reference does not describe

that the patch-containing packaging pouch will have a relative humidity of 25% or less at 25°C as recited in independent claim 1 and incorporated within presently pending claim 7. The Kanois et al. reference does not mention the relationship between relative humidity and the type of drug to be used in the transdermal formulation, and therefore, does not remedy the deficiencies of the Wilking reference. Accordingly, neither the Wilking nor the Kanios et al. references, taken in combination or alone, render presently pending claim 7 obvious.

As such, neither of the prior art references cited by the Examiner teach all of the limitations of the presently pending claims, as required by In re Wilson. Further, there is no suggestion in the Wilking or Kanois et al. references that would motivate a person of ordinary skill in the art to read these missing elements into either of the prior art references. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness. Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 7.

3. Rejection of claim 9 under 35 U.S.C. § 103(a)

The Official Action states that claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilking in view of Takayuki et al (JP 61-73547).

RESPONSE

Applicants respectfully traverse this rejection of claim 9. The cited references do not establish a *prima facie* case of obviousness against presently pending claim 9. The requirements for establishing a *prima facie* case of obviousness, as previously

discussed in Section 2, are incorporated herein by reference in their entirety.

A. The Presently Claimed Invention

As previously discussed, the presently claimed invention as exemplified by currently amended independent claim 1 is directed to:

> A patch-containing packaging pouch comprising: a packaging pouch; and a patch, housed within the packaging pouch, in which a pressure-sensitive adhesive layer is formed on one side of a support, wherein the pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and bisoprolol or a pharmaceutically acceptable salt thereof, wherein the content of bisoprolol is 1 to 50% by mass in the pressure-sensitive adhesive composition, and relative humidity inside the packaging pouch at 25°C is maintained at 25% or less.

Dependent claim 9 incorporates the features recited in independent claim 1, and further recites "the packaging pouch has layer formed from polyacrylonitrile on the innermost side of said packaging pouch."

B. The Teachings of the Wilking Reference

As previously discussed in Section 1, the Wilking reference describes a transdermal drug delivery device containing a substantially water free carrier, a dissolved drug, a dessicant package, and a product package substantially impermeable to water vapor.

C. The Teachings of the Takayuki et al. Reference

The Takayuki et al. reference describes "an anti-inflammatory, analgesic drug packaging body formed by affixing a peel-off protective film configured from a polyacrylonitrile-based resin on the drug-coated surface of a film-like or sheet-like anti-

inflammatory, analgesic drug, and packaging and hermetically-sealing the same in a bag having an innermost layer of polyacrylonitrile-based resin which forms the innermost layer of the bag." See Takayuki et al. at page 2.

D. No *prima facie* Case of Obviousness has Been Shown by the Examiner

Neither the Wilking nor Takayuki et al. references, taken alone or in combination, disclose all of the limitations of the presently pending claims, as required by In re Wilson. In particular, the Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the innermost layer of the packaging pouch of Wilking to include a layer of polyacrylonitrile-based resin as taught by Takayuki et al. in order to keep moisture to a minimum with the package." See page 6 of the Official Action. However, neither the Wilking nor the Takayuki et al. references disclose the drug, bisoprolol or a pharmaceutically acceptable salt thereof, as required by presently pending claim 9.

Further, neither of the cited references discloses that the specific content of bisoprolol in the pressure-sensitive adhesive composition is 1-50% by mass as required by presently pending claim 9. Nowhere in either of the prior art references cited by the Examiner is there any mention of the preferred content of any drug to be used in the aforementioned transdermal formulations. The preferred content of 1-50% by mass in the present pressure-sensitive adhesive composition is specific to bisoprolol, is not well known to persons of ordinary skill in the art, and is not at all recognized by either the Wilking or Takayuki et al. references.

As previously discussed in Section 1, the Wilking reference does not describe that the patch-containing packaging pouch will have a relative humidity of 25% or less at 25°C as required by the presently pending claims. The Takayuki et al. reference does not mention the relationship between relative humidity and the type of drug to be used in the transdermal formulation, and therefore, does not remedy the deficiencies of the Wilking reference. Accordingly, neither the Wilking nor the Takayuki et al. references, taken in combination or alone, render presently pending claim 9 obvious.

As such, neither of the prior art references cited by the Examiner teach all of the limitations of the presently pending claims, as required by In re Wilson. Further, there is no suggestion in the Wilking or Takayuki et al. references that would motivate a person of ordinary skill in the art to read these missing elements into either of the prior art references. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness. Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 9.

CONCLUSION

Based upon the above remarks and amendment, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw all rejections and allow all pending claims in this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,
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